

### **REMARKS**

Claims 16-30 are currently pending in this application. Claims 1-15 were previously cancelled. In this Amendment, which is submitted in response to the Office Action mailed on April 6, 2007, Applicants have amended claims 16 and 30, have cancelled claims 17-19, and have added new claims 31-39. No new matter has been added by these amendments.

The Office Action asserts several rejections to claims 16-30. Particularly, the Office Action asserts rejections under 35 U.S.C. § 112, second paragraph, indefiniteness; 35 U.S.C. § 112, first paragraph, enablement; and 35 U.S.C. § 103. In view of the amendments to the claims and remarks below, Applicants respectfully request that the rejections asserted in the Office Action be reconsidered and withdrawn, and that a Notice of Allowance be issued.

#### **Rejection under 35 U.S.C. § 112, Second Paragraph, Indefiniteness**

Claim 17 has been rejected under 35 U.S.C. § 112 as purportedly being indefinite. Since claim 17 has been cancelled, this rejection is now moot. For this reason, Applicants respectfully request that this rejection be withdrawn.

Claim 30 has been rejected under 35 U.S.C. § 112 as purportedly being indefinite because of claim 30's recitation of "60." "60" has been stricken from claim 30. For this reason, Applicants respectfully request that this rejection be withdrawn.

#### **Rejection under 35 U.S.C. § 112, First Paragraph, Enablement**

Claims 16-26 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly failing to enable one skilled in the art to carry out the claimed invention. In this rejection, the Examiner states that the claimed composition is enabling for treating particular or specific immune system related disorders, and particular or specific autoimmune diseases. Claim 16, as amended, and claims 20-30, *vis-à-vis* their dependency on claim 16, are directed to treating or preventing particular classes or particular types of immune system related disorders and autoimmune diseases. Particularly, the claimed invention is directed to treating or preventing "immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection ...."

Section 112, first paragraph, requires that a specification enable one skilled in the art to make and use the claimed invention. A specification fails to meet this requirement if the specification fails to provide sufficient information regarding the claimed subject matter to enable a skilled artisan to make and use the claimed invention. To determine if sufficient information is provided, one must inquire whether the claimed invention can be practiced without undue experimentation. MPEP § 2164.01. That some experimentation may be required is not fatal because the issue is whether the experimentation is undue. *In re Vaeck*, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). However, “if multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.” MPEP § 2164.01(c).

The invention as recited in the amended claims is enabled by the specification. The specification teaches that the “administration of acid oligosaccharides (relatively) stimulates Th1 response and lowers Th2 cytokine release (e.g. IL-10, IL-4 and IL-5).” (Specification at page 3, lines 21-23). The specification further teaches that the “administration of a combination of acid oligosaccharide and neutral oligosaccharide synergistically stimulates the immune-system, particularly by lowering the Th2 response and increasing the Th1 response.” (Specification at page 3, lines 23-25).

Th1 cells predominately produce cytokines, which stimulate a cellular immune response (IFN- $\gamma$ , IL-12, IL-2). In contrast, Th2 cells predominately produce IL-4, IL-5 and IL-10. These cytokines boost an IgE-mediated allergic reaction and inflammation and are thought as well to be involved with recruitment, proliferation, differentiation, maintenance and survival of eosinophils (i.e. leukocytes that accept an eosin stain), which can result in eosinophilia. (Specification at page 1, lines 9-15).

Eosinophils are white blood cells involved in combating infections by parasites, and mechanisms involved in controlling allergic response, among other things. Eosinophilia, a state of having a high concentration of eosinophils, is a condition associated with allergic disorders, among other things.

The invention as claimed is directed to a method of treating immune system related disorders and autoimmune diseases that are treatable or preventable via increasing the Th1 response and lowering the Th2 response. According to MPEP § 2164.01 (c), the specification need only enable one skilled in the art to carry out at least a method of treating

and/or preventing an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection because each of these immune system-related disorders can be treated by increasing the Th1 response and lowering the Th2 response. As admitted in the Office Action, the specification accomplishes this (see Office Action at page 3).

For these reasons, Applicants respectfully request that this rejection be reconsidered and withdrawn.

### **Rejection under 35 U.S.C. § 103**

Claims 16-30 have been rejected under 35 U.S.C. § 103 as being unpatentable over Stahl *et al.* (U.S. Publ. Pat. App. No. 2003/0022863 A1) (hereinafter referred to as "Stahl"). For a reference to obviate a claimed invention, it must either expressly, implicitly or inherently teach each and every element of the claimed invention. MPEP § 2112. According to the Office Action, Stahl does not teach "the administration of their composition for preventing or treating an immune system-related disorder in a mammal." (Office Action at page 8). Since this element is not taught by Stahl, Stahl can only obviate the claimed invention if the missing element is common knowledge within the art, or is inherently taught by the cited reference. In this case, neither is true.

The missing element is not common knowledge within the art. "In limited circumstances, it is appropriate for an examiner to take official notice of facts not in the record or to rely on 'common knowledge' in making a rejection, however such rejections should be judiciously applied." MPEP § 2144.03. These circumstances are even more limited when there is no documentary evidence to support the assertion that the officially noted limitation is common knowledge within the art. MPEP § 2144.03. "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of *instant and unquestionable* demonstration as being well-known." MPEP § 2144.03 (emphasis added).

In this case, a method for the treatment and/or prevention of the claimed immune system-related disorders is not capable of instant and unquestionable demonstration as being well-known within the art because the inventors were the first to discover this method. As admitted, Stahl does not disclose this method. The claimed method would not

be within the common knowledge of a skilled artisan because had it been, Stahl would have disclosed it and claimed it. Instead, Stahl only disclosed a composition for reducing and/or blocking the adhesion of pathogenic substances and organisms to eucaryotic cells (see Stahl ¶ 0001). A skilled artisan would not instantly and unquestionably know that this preparation also increases Th1 and decrease Th2 responses, or is suitable as a method of treating and/or preventing the claimed immune system-related disorders.

Even under the doctrine of inherency, Stahl still does not teach or suggest the claimed invention. Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will be deemed to anticipate a subsequent claim if the missing element is “necessarily present” in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed.Cir. 2002), *quoting* *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed.Cir. 1991). Thus, inherent anticipation requires that the missing descriptive material be “necessarily present,” not merely probably or possibly present, in the prior art. *Rosco*, 304 F.3d at 1380, *quoting* *Trintec Indus., Inc. v. Top U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed.Cir. 2002), *citation omitted*.

In *Astrazeneca v. Mutual Pharmaceutical Co.*, the Court found that a reference, which disclosed using PEG 400, did not disclose using a solubilizer, and therefore did not anticipate the claims of the subject patent, even though PEG 400 was known to be capable of functioning as a solubilizer. 278 F.Supp.2d 491, 512 (E.D. Pa 2003). The Court reasoned that merely because PEG 400 was capable of functioning as a solubilizer does not mean that the reference necessarily used PEG 400 as a solubilizer. *Id.*

Nothing within Stahl suggests that Stahl’s composition necessarily treats and/or prevents the claimed immune system-related disorders, or increases the Th1 response while decreasing the Th2 response because Stahl is not concerned with the treatment and/or prevention of the claimed immune system-related disorders. Instead, Stahl is only concerned with reducing and/or blocking adhesion of pathogenic substances. Even assuming that Stahl’s teaching does increase the Th1 response and decrease the Th2 response, it is not inherently disclosed in Stahl because the Th1 and Th2 responses are unrelated to reducing and/or blocking the adhesion of pathogenic substance. Therefore, it is not necessarily, and is not inherently disclosed. For this reason, Stahl does not inherently disclose a method of treating and/or preventing the claimed immune system-related disorders.

For these reasons, Applicants respectfully submit that the claimed invention is patentable over Stahl, and respectfully request that this rejection be reconsidered and withdrawn.

### CONCLUSION

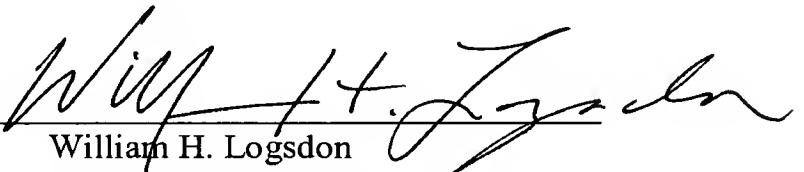
In addition to the remarks above, Applicants would like to call to the attention of the Patent Office that claims directed to a method for the treatment and/or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, in a related European Union patent application have been allowed.

In view of the foregoing amendments and remarks, Applicants respectfully submit that all pending claims in the instant application are patentable over the prior art and are in condition for allowance. Accordingly, reconsideration and withdrawal of the asserted rejections and a Notice of Allowance are respectfully requested.

Should the Examiner have any questions or concerns, the Examiner is invited to contact Applicants undersigned attorney by telephone at 412-471-8815.

Respectfully submitted,

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